

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 9, 2008 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 has been amended to state the device is complaint *and elastic* (emphasis added). The current specification clearly states the device is inelastic as can be seen in Paragraphs 0061, 0063 and 0071 of the Pre-Grant Publication of this application. Therefore the addition of "elastic" to the claim constitutes new matter.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman et al (6,224,540 B1) in view of Gordon et al (5,336,253).

Lederman et al disclose a passive girdle for constraining heart expansion and further disclose accessing the heart (the heart has to be accessed in order to place jacket 30 on the heart); selecting a device (30) sized to be placed on the diseased heart; placing the device (30) on the heart, the device (30) comprising compliant and elastic (as explained in the Applicant's remarks filed on June 9, 2008, regarding the term "elastic") biocompatible material (33) configured to engage a surface of the heart to passively constrain circumferential expansion of the heart (See Column 5, lines 35-36); securing the device (30) on the heart (See Column 5, lines 52-55); the device (30) is secured to the heart using sutures (See Column 5, lines 52-55, attaching the device at 4-6 points along the A-V groove suggests the use of sutures because an adhesive would be incompatible on a beating heart); adjusting the device (30) to snugly conform to the external geometry of the heart (See Column 5, lines 55-57); and the device (30) is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume (See Column 5, lines 26-31, see explanation above).

Lederman et al however fail to disclose passing an electrical element into the heart; passing an electrical current to the heart using the electrical element, the current selected to apply and electrical therapy to the heart; the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy.

Gordon et al disclose a pacing and defibrillation lead for providing therapy to a heart and further disclose passing an electrical element into the heart (see Column 2, lines 55-60; Column 3, lines 17-18; Column 4, lines 30-33; the lead is run through the superior vena cava and into the right ventricle, in order to place the electrode at the apex of the heart); passing an electrical current to the heart using the electrical element, the current selected to apply an electrical therapy to the heart (see Column 2, lines 55-60; and Column 3, lines 61-68); the electrical elements (10) are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy. See also: Column 2, lines 40-48; and Column 6, lines 34-54.

To provide the means of Lederman et al with an electrotherapy means would have been obvious to one of ordinary skill in the art, in view of the teachings of Gordon et al, since all of the claimed elements were known in the prior art and one skill in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e. one skill in the art would have recognized that the electric therapy as taught by Gordon et al

would provide the heart jacket of Lederman et al with an additional means of therapy to a heart already weakened by cardiomyopathy.

### ***Response to Arguments***

6. Applicant's arguments filed June 9, 2008 have been fully considered but they are not persuasive.

The Applicants argue that neither Lederman et al nor Gordon et al teach the currently amended claims. The Examiner respectfully disagrees. As discussed above, the current claims are not supported by the current specification because the material is not elastic. Furthermore, the explanation provided by the Applicants with respect to the elasticity of the current invention is not supported by the definition of elastic. The mesh design of the current invention (utilizing inelastic material) allows the device to elongate in one direction in response to a force (stretching), just as the plastic rings of Lederman et al would allow. Therefore the rejection is being maintained.

### ***Conclusion***

7. This is a RCE of applicant's earlier Application No. 09/880576. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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